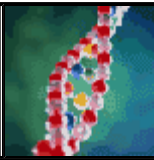


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The Year of the Stem Cell

George Annas Talks About the Future of Stem Cell Research in America
by Sujatha Byravan

GeneWatch: With Bill Frist's support for stem cell research using embryos left over from fertility clinics, we might be looking at a major shift in political support for this kind of research in the United States. This may lead to the Senate's passage of HR 810. If this bill is passed by Congress, what do you think its impact would be on the politics of stem cell research and cloning in the U.S.?

George Annas: I think it will have a major impact, even though it's a very limited bill. It is major because it shows for the first time in the Bush presidency that the Congress disagrees with him about something substantial, and that disagreement is in an area of research that opinion polls consistently show the public wants to pursue. A number of states have decided they are going to encourage this kind of research, as well. This is part of a reaction against the original Bush policy of not funding any embryonic stem cell research on any embryos created after his speech on August 9, 2001. It is also a direct rejection of the ethical foundation of that policy, specifically that taxpayer money should not be spent on anything that conflicts with the moral beliefs of a significant segment of the American population. Of course, limiting human embryonic stem cell research to "spare" IVF embryos is a political, not an ethical or moral, compromise. The moral status of the human embryo does not depend upon how or why it was created in the first place.

Do you think passage of HR 810 would propel other bills forward, for instance, the one introduced by Dianne Feinstein that would ban reproductive cloning?

It's hard to say. The concerns about reproductive (though I prefer the adjective "replicative") cloning don't arise until you actually do somatic cell nuclear transfer (SCNT*), and HR 810 would not fund that kind of research at all. If the President doesn't veto this bill, or if his veto is overridden, the next question Congress will have to face is whether to approve federal funding for SCNT, which I do not believe it can or should do without outlawing reproductive cloning, that is, cloning to make a baby.

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According to many scientists, embryos left over from IVF clinics may be too old or damaged to be useful in research, and thus more embryos would be needed. Scientists are therefore seeking egg donations from women for stem cell research. What can be done to protect women from the risks associated with multiple egg extraction procedures?

First of all, HR 810 would not allow funding for research using such eggs. It explicitly permits only embryos left over from IVF clinics, and which the couple agrees would not be used for reproduction, for themselves or others. So the potential sources of embryos that can be used for research under the federal bill are actually very limited.

I don't think anyone is convinced that there will be sufficient IVF embryos left over to do the research people want to do today, and, of course, they cannot be used to do SCNT. We are going to have to wait to find out, but there is some data that indicates that many couples are willing to donate their left over, now-frozen, embryos. But there is a difference between that hypothetical question and what these couples will end up doing in real life, so it is still too early to tell whether the number of embryos is going to be sufficient.

California and Massachusetts, two states that recently passed relevant legislation that will encourage SCNT, will need to put in place some system to help ensure that women can donate their eggs without being exploited, and that the procedure is done safely. The Massachusetts legislation explicitly states that women cannot be paid for donating eggs, as a way of avoiding financial coercion on the donors. Many people think that donors will not necessarily have to be paid as an incentive; women who have relatives with diseases that could theoretically be cured or helped by the ultimate products produced by stem cell research would be more than happy to take drugs to super-ovulate for multiple egg extraction procedures. Again, much of this remains to be seen. But, as you said, the issue is how do we protect women who are undergoing a procedure that is not for their benefit in any way, and could be physically harmful to them? At the minimum, each potential donor should have her own personal physician, whose job, of course, is to protect her health and welfare.

Can egg donation, in this case, be defined as an issue of informed consent, considering that there isn't much information to base consent upon?

There are two schools of thought here. On one hand, people claim that multiple egg extraction procedures are not research in the sense that we routinely perform them in IVF clinics for women who want to have babies, or who want to donate eggs to others to be used to have children. On the other hand, there is no good long-term data on the health effects of the

drugs used to induce super-ovulation. Though it doesn't look like the risk is extremely high, it raises the following question: if there is any risk at all, how can a physician justify subjecting a woman to that risk, considering (unlike in IVF) she can get no medical benefit at all from the procedure? And considering the short-term prospects of stem cell research (unlike donation to help produce a child), it's unlikely that a sick member of her family could get a medical benefit from such a procedure either. Whether a physician should even perform the procedure purely to help produce eggs for research is a medical ethics issue that has not been sufficiently addressed.

I think proposals to try to figure out other ways to get eggs from women, for example, when they are having their ovaries removed, or during some other procedure that would not expose them to additional risk, make a lot of sense. I think you would need to prove that non-risk alternatives don't work before moving on to recruiting women to be egg donors. Again, this issue only comes up in SCNT research.

Even if Congress supports stem cell research with HR 810, scientists still want to do SCNT as part of research on diseases like juvenile diabetes or Parkinson's. We know that many of the claims about SCNT to cure these diseases are exaggerated, but do you think that there is a way to move forward without supporting religious zealots or corporate interests, by carefully investigating the promise of this technology?

I think there is, but it will be very difficult to do it correctly. One of the biggest problems that we have in the United States is that there is no national public review board, there is no transparency, there is no one place where the scientists who want to do research using human embryos can go to say, "Here is the research I want to do, this is how I'm going to do it, do you think that this is a worthwhile proposal to be supported?" There isn't a body to which one could meaningfully say, "I'm going to do this research in an open enough way to guarantee that none of the embryos I make can be used to make a baby, but they will only be used to make stem cells for research."

Even though I have a lot of respect for the work that went into the Guidelines on Human Embryonic Stem Cell Research that was put out by the Institute of Medicine in April 2005, this is where I think they missed the boat. The group recognized that there should be national standards to guide human embryonic stem cell research, but they ultimately failed to propose a meaningful way to assure this. Although they said there should be some national policy review, they simultaneously said they didn't believe that there should be some national body that would essentially function as a national institutional review board, or IRB, that would have

to approve all embryonic stem cell research protocols before they could be undertaken. Instead, they concluded that local, hospital, or corporate review bodies should be used. This is somewhat astonishing since obviously we have no experience in reviewing this area of research at all — at any level. Human embryo research is the most controversial research area in the United States and worldwide, and it would seem that rules for it should be developed and applied in a uniform manner — and this requires a national review process. The very idea that local IRBs (even if specially constituted to just review embryo research) have the expertise, or could even develop the expertise, to approve these types of research is ludicrous on its face.

There is probably a lot of resistance in the Institute of Medicine to suggest a national review board, and it is understandable, especially under the Bush administration. Nonetheless, I think that kind of governance is necessary, whether or not the research is ultimately federally funded.

Given that we don't yet have this kind of regulatory structure in place, do you then think that rejecting SCNT is the only ethical position one can take at this point?

Yes, although I think there is one possible exception to that position. Large states might be able to set up their own statewide review boards and oversight procedures. I don't know if it is going to, but California could certainly put in place procedures that would meet most of the conditions I've set out for SCNT research. The only condition it wouldn't be able to meet is having a national standard for regulation. Nonetheless, the individual states could theoretically work together to develop and adopt what would be de facto national standards. That is to say, if Massachusetts and California, for example, agreed on the same standards and implemented them in a public, statewide review process, that could be acceptable. But without some kind of statewide review, I think that you can't ethically do this kind of research, as there currently simply aren't any widely-accepted standards.

Would regulations on this kind of research include regulation on chimeras?

I would include any kind of research that involves creating (or destroying) human embryos.

Private research institutions, such as Harvard University, or states like California, Massachusetts, and New Jersey are bypassing federal stem cell funding restrictions. What, in your opinion, are the long-term political consequences of this?

First of all, no state, even California, is going to be able to provide sufficient funding for research for any length of time. I just don't think there will be many long-term consequences for states funding stem cell research, because first, they can't afford it, and second, this situation is an artifact of the current federal administration's funding policy.

Nonetheless, the fact that states like California have changed their constitutions, and institutions like Harvard have been able to successfully raise private capital, indicates the erosion of the basic idea that the federal government should be the primary funding — and regulatory — source for very innovative research. Such research should be publicly approved, either through an IRB, or some kind of a scientific and ethical review at the National Institutes of Health. The danger of cutting-edge research, especially research that can be problematic if not done according to high ethical standards, is that it will go into the underground, and essentially secret, private sector. There, it will become akin to classified military research, where no one knows about it until the consequences are unleashed on the world. It's potentially very dangerous.

So are your main concerns about private and state initiatives for stem cell research related to poor regulation and oversight, and private gain from public funding?

Public regulation and fair distribution of benefits are both important. But neither are related exclusively to embryonic stem cell research. The concern about the private benefits from publicly funded research, for example, is a generic one in terms of our inability, in the United States, to have a reasonable system of national health insurance, to distribute the medical fruits of research in a fair and equitable manner. That's not an issue we should be taking out just on embryonic stem cell research, but it is one that needs to be addressed. Nonetheless, we should prohibit restrictive patenting. But the biggest concern is that this research will be done without public accountability because it will almost certainly have a direct impact on not just what we will be able to do, but more importantly about how we think about ourselves as humans, including the meaning of health and life itself.

Would you feel comfortable making a prediction about the status of stem cell research 10 years down the road?

Considering that there is not enough information to make a prediction for one year down the road, I couldn't say I'm comfortable making a prediction for ten. I will say that we will know a lot more next year about what direction we are going in, as we'll know what happened with the proposed legislation at the federal level, and how things are going in Massachusetts under its new stem cell research statute, and whether

things in California are moving or are at a standstill. It's going to be a very important year for embryonic stem cell research in the United States.

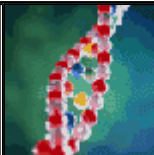
Is there anything else you would like to add about cloning and stem cell research?

I think it's very important to make the distinction between using human embryos produced by SCNT to make medicine and using them to make babies. If you want to support the former and not the latter (and this is a worldwide consensus position), you are absolutely required to have serious regulatory transparency systems in place, otherwise SCNT research to make medicine will inevitably lead to replicative cloning to make babies. This means, I think, having rules that include the prohibition of creating SCNT embryos by anyone involved in IVF or fertility treatment, doing SCNT research by anyone involved in IVF or fertility treatment, prohibiting the freezing of SCNT embryos — so they cannot be “stockpiled” or transported for possible reproductive use, and, of course, prohibiting any commerce in embryos created by SCNT. The only one of these minimal regulatory prohibitions that is currently agreed upon is the prohibition of commerce, but we will need the others as well if we want to move forward with SCNT research.

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